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Part V

Department of Health and Human Services

Public Health Service

42 CFR Part 59
Standards of Compliance for Abortion-Related Services in Family Planning Service Projects; "Gag Rule" Suspension; Rule and Proposed Rule

Office of the Secretary

Family Planning Service Projects; Transplantation of Human Fetal Tissue and Importation of the Drug Mifepristine; Notice

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

42 CFR Part 59

Standards of Compliance for Abortion-Related Services in Family Planning Service Projects

AGENCY: Public Health Service, DHHS.

ACTION: Interim rule: suspension of effectiveness.

SUMMARY: This Interim rule suspends the rules issued in 1988 establishing standards for compliance by family planning services projects assisted under Title X of the Public Health Service Act with the statutory provision prohibiting abortion as a method of family planning in programs funded under that title. The rules, popularly known as the "Gag Rule", have been the focus of much litigation and controversy, and because the Secretary believes that the Rule inappropriately restricts grantees, she accordingly suspends them and, elsewhere in this issue of the **Federal Register**, proposes to return the program to the regulatory provisions and compliance standards operative prior to their issuance. This action is also consistent with a Memorandum issued by the President on January 22, 1993. During the pendency of the proposed rulemaking, the compliance standards that were in effect prior to the issuance of the Gag Rule will be used to administer the program.

EFFECTIVE DATE: February 5, 1993.

FOR FURTHER INFORMATION CONTACT: Mr. Gerald Bennett, 202–690–8335.

SUPPLEMENTARY INFORMATION: The Secretary of Health and Human Services below suspends the rules issued on February 2, 1988. 53 FR 2922. Those rules, popularly known as the "Gag Rule," established standards for compliance by family planning services projects funded under Title X of the Public Health Service Act, 42 U.S.C. 300, *et seq.*, with the statutory prohibition on the use of funds under that title "in programs where abortion is a method of family planning." 42 U.S.C. 300a–6. The prior history of the controversy surrounding sec. 300a–6 is fully described in the preamble to the 1988 rules.

Since their issuance, the February 2, 1988 rules have been the focus of much litigation and controversy. Although they were upheld by the Supreme Court in *Rust* v. *Sullivan*, 111 S.Ct. 1759 (1991), a subsequent interpretation of the rules by the Bush Administration, under which physicians would have been permitted to counsel and refer Title X patients for abortion counseling and referral but other project employees would not have been permitted to do so, was recently held to be impermissible by the United States Court of Appeals for the District of Columbia Circuit. *National Family Planning and Reproductive Health Ass'n.* v. *Sullivan*, 979 F.2d 227 (D.C. Cir. 1992). This recent decision, together with the change of Administrations, has left the current status of the 1988 Title X rules unclear.

On January 22, 1993, President Clinton sent to the Secretary a memorandum on this matter, which is published elsewhere in this issue.

The Secretary's action herein is based, in part, upon her conclusion that the "Gag Rule" is an inappropriate implementation of the Title X statute because it unduly restricts the information and other services provided to individuals under this program. Therefore, the Secretary suspends the 1988 rules and announces that, on an interim basis, the agency's nonregulatory compliance standards that existed prior to February 2, 1988, including those set out in the 1981 Family Planning Guidelines, will be used to administer the Family Planning Program.

Under these compliance standards, Title X projects would be required, in the event of an unplanned pregnancy and where the patient requests such action, to provide nondirective counseling to the patient on options relating to her pregnancy, including abortion, and to refer her for abortion, if that is the option she selects. However, consistent with the prior long-standing Departmental interpretation of the statute, Title X projects would not be permitted to promote or encourage abortion as a method of family planning, such as engaging in pro-choice litigation or lobbying activities. Title X projects would also be required to maintain a separation (that is more than a mere exercise in bookkeeping) of their project activities from any activities in which they engage that promote or encourage abortion as a method of family planning.

As noted in the President's memorandum, these compliance standards were in effect for a considerable period of time prior to 1988, and the Department believes that they are generally well-understood within the Title X provider community.

Notice and comment and delay in effective date are waived for good cause and because delay would be impracticable and unnecessary and contrary to the public interest. The issues involved in this matter are well known and have been extensively debated. Based on that record, it is the conclusion of the Secretary that: (1) Repeated attempts by the Bush and Reagan Administrations to enforce and modify the "Gag Rule" have created considerable confusion about the status of the regulations and the policy underlying them and, therefore, a substantial health risk to potential recipients of Title X program services; (2) suspension of the regulation, though tantamount to a statement of enforcement policy, is preferable because it provides clearer guidance and more certainty to the grantees and to women making family planning decisions; (3) the 1988 regulation would require many grantees to make extensive and expensive alterations in their physical facilities and organizational structures. To require those changes in the face of the proposed reversal of those rules is impracticable and contrary to the public interest; (4) evidence exists that the continued failure to provide women with complete and accurate medical information will result in significant health risks. The Notice of Proposed Rulemaking being contemporaneously published will give those with differing views on the matter an opportunity to rebut this conclusion. In the interim, the Secretary believes that it is important not to continue the embargo of important health information; (5) the original interpretation of section 1008, which prohibited the use of Title X funds in programs where abortion is a method of family planning, did not include a prohibition on non-directive counseling on abortion; moreover, Congress's repeated attempts—vetoed by President Bush—to amend Title X to eliminate the restrictions justify suspension of the Rule while the regulations are being revised to further the purposes of Title X, as required by statute. For all of these reasons, as well as the reasons set out in the President's Memorandum, this Interim Rule is effective upon publication. Regional officials are being informed of this action, and will notify all present Title X grantees of the suspension of the 1988 rules.

List of Subjects in 42 CFR Part 59

Family planning—birth control, Grant programs—health, Health facilities, Low-income families.

Dated: January 29, 1993.

Audrey F. Manley,

Acting Assistant Secretary for Health.

Approved: February 1, 1993.

Donna E. Shalala,

Secretary.

For the reasons set out in the preamble, the Secretary amends subpart A of 42 CFR part 59 as follows:

PART 59—[AMENDED]

1. The authority for subpart A of part 59 continues to read as follows:

Authority: 42 U.S.C. 300a–4.

§ 59.2 [Suspended]

2. The following definitions in § 59.2 are suspended: The definitions of "Family planning", "Grantee", "Prenatal care", "Program", "Project", "Title X", "Title X program", and "Title X project."

§§ 59.7–59.10 [Suspended]

3. Sections 59.7 through 59.10 are suspended.

4. Additionally, the miscellaneous amendments to § 59.5 on 53 FR 2944, paragraphs 3 and 4, and the miscellaneous amendments appearing on 53 FR 2946, paragraph 6, are suspended.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

42 CFR Part 59

Standards of Compliance for Abortion-Related Services in Family Planning Service Projects

AGENCY: Public Health Service, DHHS.

ACTION: Proposed rule.

SUMMARY: This document proposes revocation of the rules issued in 1988 establishing standards for compliance by family planning services projects assisted under Title X of the Public Health Service Act with the statutory provision prohibiting abortion as a method of family planning in programs funded under that title. The rules, popularly known as the "Gag Rule", have been the focus of much litigation and controversy, and because the Secretary believes that the Rule inappropriately restricts grantees, she accordingly proposes below to revoke them and return the program to the compliance standards operative prior to their issuance. This action is also consistent with a memorandum issued by the President on January 22, 1993.

DATES: Comments must be received on or before April 6, 1993.

ADDRESSES: Comments must be in writing, and must be sent to: Mr. Gerald Bennett, Acting Deputy Assistant Secretary for Population Affairs, Department of Health and Human Services, P.O. Box 23783, Washington, DC 20026–3783.

Comments will be available for public inspection during normal business hours at this address. PHS will take appropriate steps, where necessary, to afford individuals with disabilities and equal opportunity to comment.

FOR FURTHER INFORMATION CONTACT: Mr. Gerald Bennett, 202–690–8335.

SUPPLEMENTARY INFORMATION: The Secretary of Health and Human Services proposes below rules revoking the rules issued on February 2, 1988. 53 FR 2922. Those rules, popularly known as the "Gag Rule," established standards for compliance by family planning services projects funded under Title X of the Public Health Service, 42 U.S.C. 300, *et seq.*, with the statutory prohibition on the use of funds under that title "in programs where abortion is a method of family planning." 42 U.S.C. 300a–6. The prior history of the controversy surrounding sec. 300a–6 is fully described in the preamble to the 1988 rules.

Since their issuance, the February 2, 1988 rules have been the focus of much litigation and controversy. Although they were upheld by the Supreme Court in *Rust* v. *Sullivan*, 111 S.Ct. 1759 (1991), a subsequent interpretation of the rules by the Bush Administration, under which physicians would have been permitted to counsel and refer Title X patients for abortion counseling and referral but other project employees would not have been permitted to do so, was recently held to be impermissible by the United States Court of Appeals for the District of Columbia Circuit. *National Family Planning and Reproductive Health Ass'n.* v. *Sullivan*, 979 F.2d 227 (D.C. Cir. 1992). This recent decision, together with the change of Administrations, has left the current status of the Title X rules unclear.

On January 22, 1993, President Clinton sent to the Secretary a memorandum on this matter, which is published elsewhere in this issue.

The Secretary's action herein is based, in part, upon her conclusion that the "Gag Rule" is an inappropriate implementation of the Title X statute because it unduly restricts the information and other services provided to individuals under this program. Therefore, the Secretary proposes below to revoke the 1988 rules and to readopt the Title X rules as they existed prior to February 2, 1988. The Secretary believes that the prior rules provide an appropriate approach to implementing Title X. In addition, the Secretary intends to reinstate the compliance standards that existed prior to that date, including those set out in the 1981 Family Planning Guidelines and in individual policy interpretations. (These compliance standards are being used on an interim basis because of the suspension of the "Gag Rule" discussed below.) Under these compliance standards. Title X projects would be required, in the event of an unplanned pregnancy and where the patient requests such action, to provide nondirective counseling to the patient on all options relating to her pregnancy, including abortion, and to refer her for abortion, if that is the option she selects. However, consistent with the long-standing Departmental interpretation of the statute, Title X projects would not be permitted to promote or encourage abortion as a method of family planning, such as by engaging in pro-choice litigation or lobbying activities. Title X projects would also be required to maintain a separation (that is more than a mere exercise in bookkeeping) of their project activities from any activities that promote or encourage abortion as a method of family planning.

As noted in the President's memorandum, these regulations and compliance standards were in effect for a considerable period of time prior to 1988, and the Department believes that they are generally well-understood within the Title X provider community. The rules proposed below are thus the Title X rules as in effect on February 1, 1988. It is recognized that some of the other regulations cross-referenced in the rules below may no longer be operative or citations may need to be updated. However, such housekeeping details will be addressed in the final rules.

The Secretary solicits comment on the proposals described above and suggestions for alternatives that will be consistent with the statute while promoting the interests of public health. Due to the considerations outlined in the President's memorandum, the Secretary's determination that the 1988 rules do not represent good public health policy, and due to the confusion and hardship caused by the 1988 rules, the Secretary has also, for the duration of the rulemaking period, suspended the 1988 rules. This action is being implemented pursuant to an Interim Rule which has been published separately in the Federal Register. Regional officials are being informed of this action, and will notify all present Title X grantees of the suspension of the 1988 rules.

Regulatory Flexibility Act and Executive Order 12291

The proposed rules would generally lessen the existing procedural and reporting requirements for covered entities. The Department has determined that the impact would not approach the annual $100 million threshold for major economic consequences as defined in E.O. 12291. Therefore, a regulatory impact analysis is not required.

Consistent with the provisions of the Regulatory Flexibility Act (5 U.S.C. 605(b)), the Secretary certifies that this rule will not have a significant economic impact on a substantial number of small entities.

Executive Order 12612

E.O. 12612 requires that a Federalism Assessment be prepared in any cases in which proposed policies have significant federalism implications as defined in the Executive Order. Among the types of actions which can have such implications are federal regulatory actions which preempt State law. The Department does not intend or interpret the rules proposed below as imposing

additional costs or burdens on the States or preempting State laws, nor are the rules inconsistent with any of the principles, criteria or requirements established by this Executive Order. In fact, it is anticipated that the rules will lessen present reporting and other burdens and costs. Therefore, these proposed rules would comply with E.O. 12612.

Paperwork Reduction Act of 1980

This proposed rule contains no information collections which are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1980.

Family Impact

The proposed rules have been reviewed in conformance with E. O. 12606. The proposed rules below would get Title X clinics out of the middle of the abortion decision, returning it to the decision-making processes of the title X clients and their families and enable them to act in what they have determined to be their own best interests. It would thus promote the stability of the family, support parental influence, reduce governmental intrusion on family activities, enhance the role and autonomy of the family in decision-making, and require less Federal involvement in monitoring activities than would the present rules. The rules below also support the message to young people that they should engage in responsible decision-making about their reproductive health and choices.

List of Subjects in 42 CFR Part 59

Family planning—birth control, Grant programs—health, Health facilities, Low-income families.

Dated: January 29, 1993.

Audrey F. Manley,

Acting Assistant Secretary for Health.

Approved: February 1, 1993.

Donna E. Shalala,

Secretary.

PART 59—[AMENDED]

For the reasons set out in the preamble, it is proposed to revise subpart A of 42 CFR part 49 to read as follows:

Subpart A—Project Grants for Family Planning Services

Sec.

Subpart A—Project Grants for Family Planning Services

Authority: 42 U.S.C. 300a–4.

§ 59.1 To what programs do these regulations apply?

The regulations of this subpart are applicable to the award of grants under section 1001 of the Public Health Service Act (42 U.S.C. 300) to assist in the establishment and operation of voluntary family planning projects. These projects shall consist of the educational, comprehensive medical, and social services necessary to aid individuals to determine freely the number and spacing of their children.

§ 59.2 Definitions.

As used in this supbart:

Act means the Public Health Service Act, as amended.

Family means a social unit composed of one person, or two or more persons living together, as a household.

Low income family means a family whose total annual income does not exceed 100 percent of the most recent Community Services Administration Income Poverty Guidelines (45 CFR 1060.2). *Low income family* also includes members of families whose annual family income exceeds this amount, but who, as determined by the project director, are unable, for good reasons, to pay for family planning services. For example, unemancipated minors who wish to receive services on a confidential basis must be considered on the basis of their own resources.

Nonprofit, as applied to any private agency, institution, or organization, means that no part of the entity's net earnings benefit, or may lawfully benefit, any private shareholder or individual.

Secretary means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom the authority involved has been delegated.

State means one of the 50 States, the District of Columbia, Puerto Rico, Guam, the Virgin Islands, American Samoa, Northern Marianas, or the Trust Territory of the Pacific Islands.

§ 59.3 Who is eligible to apply for a family planning services grant?

Any public or nonprofit private entity in a State may apply for a grant under this subpart.

§ 59.4 How does one apply for a family planning services grant?

(a) Application for a grant under this subpart shall be made on an authorized form.

(b) An individual authorized to act for the applicant and to assume on behalf of the applicant the obligations imposed by the terms and conditions of the grant, including the regulations of this subpart, must sign the application.

(c) The application shall contain—

(1) A description, satisfactory to the Secretary, of the project and how it will meet the requirements of this subpart;

(2) A budget and justification of the amount of grant funds requested;

(3) A description of the standards and qualifications which will be required for all personnel and for all facilities to be used by the project; and

(4) Such other pertinent information as the Secretary may require.

§ 59.5 What requirements must be met by a family planning project?

(a) Each project supported under this part must:

(1) Provide a broad range of acceptable and effective medically approved family planning methods (including natural family planning methods) and services (including infertility services and services for adolescents). If an organization offers only a single method of family planning, such as natural family planning, it may participate as part of a project as long as the entire project offers a broad range of family planning services.

(2) Provide services without subjecting individuals to any coercion to accept services or to employ or not to employ any particular methods of family planning. Acceptance of services must be solely on a voluntary basis and may not be made a prerequisite to eligibility for, or receipt of, any other service, assistance from or participation in any other program of the applicant.[1]

[1] Section 205 of Pub. L. 94–63 states that any (1) officer or employee of the United States, (2) officer or employee of any State, political subdivision of a State, or any other entity, which administers or

Continued

(3) Provide services in a manner which protects the dignity of the individual.

(4) Provide services without regard to religion, race, color, national origin, handicapping condition, age, sex, number of pregnancies, or marital status.

(5) Not provide abortions as a method of family planning.

(6) Provide that priority in the provision of services will be given to persons from low-income families.

(7) Provide that no charge will be made for services provided to any person from a low-income family except to the extent that payment will be made by a third party (including a Government agency) which is authorized to or is under legal obligation to pay this charge.

(8) Provide that charges will be made for services to persons other than those from low-income families in accordance with a schedule of discounts based on ability to pay, except that charges to persons from families whose annual income exceeds 250 percent of the levels set forth in the most recent CSA Income Poverty Guidelines (45 CFR 1060.2) will be made in accordance with a schedule of fees designed to recover the reasonable cost of providing services.

(9) If a third party (including a Government agency) is authorized or legally obligated to pay for services, all reasonable efforts must be made to obtain the third-party payment without application of any discounts. Where the cost of services is to be reimbursed under title XIX or title XX of the Social Security Act, a written agreement with the title XIX or title XX agency is required.

(10) (i) Provide that if an application relates to consolidation of service areas or health resources or would otherwise affect the operations of local or regional entities, the applicant must document that these entities have been given, to the maximum feasible extent, an opportunity to participate in the development of the application. Local and regional entities include existing or potential subgrantees which have previously provided or proposed to provide family planning services to the area proposed to be served by the applicant.

(ii) Provide an opportunity for maximum participation by existing or potential subgrantees in the ongoing policy decisionmaking of the project.

(11) Provide for an Advisory Committee as required by § 59.6.

(b) In addition to the requirements of paragraph (a) of this section, each project must meet each of the following requirements unless the Secretary determines that the project has established good cause for its omission. Each project must:

(1) Provide for medical services related to family planning (including physician's consultation, examination prescription, and continuing supervision, laboratory examination, contraceptive supplies) and necessary referral to other medical facilities when medically indicated, and provide for the effective usage of contraceptive devices and practices.

(2) Provide for social services related to family planning, including counseling, referral to and from other social and medical services agencies, and any ancillary services which may be necessary to facilitate clinic attendance.

(3) Provide for informational and educational programs designed to (i) achieve community understanding of the objectives of the program, (ii) inform the community of the availability of services, and (iii) promote continued participation in the project by persons to whom family planning services may be beneficial.

(4) Provide for orientation and in-service training for all project personnel.

(5) Provide services without the imposition of any durational residency requirement or requirement that the patient be referred by a physician.

(6) Provide that family planning medical services will be performed under the direction of a physician with special training or experience in family planning.

(7) Provide that all services purchased for project participants will be authorized by the project director or his designee on the project staff.

(8) Provide for coordination and use of referral arrangements with other providers of health care services, local health and welfare departments, hospitals, voluntary agencies, and health services projects supported by other Federal programs.

(9) Provide that if family planning services are provided by contract or other similar arrangements with actual providers of services, services will be provided in accordance with a plan which establishes rates and method of payment for medical care. These payments must be made under agreements with a schedule of rates and payment procedures maintained by the grantee. The grantee must be prepared to substantiate that these rates are reasonable and necessary.

(10) Provide, to the maximum feasible extent, an opportunity for participation in the development, implementation, and evaluation of the project by persons broadly representative of all significant elements of the population to be served, and by others in the community knowledgeable about the community's needs for family planning services.

§ 59.6 What procedures apply to assure the suitability of informational and educational material?

(a) A grant under this section may be made only upon assurances satisfactory to the Secretary that the project shall provide for the review and approval of informational and educational materials developed or made available under the project by an Advisory Committee prior to their distribution, to assure that the materials are suitable for the population or community to which they are to be made available and the purposes of title X of the Act. The project shall not disseminate any such materials which are not approved by the Advisory Committee.

(b) The Advisory Committee referred to in paragraph (a) of this section shall be established as follows:

(1) *Size.* The Committee shall consist of no fewer than five but not more than nine members, except that this provision may be waived by the Secretary for good cause shown.

(2) *Composition.* The Committee shall include individuals broadly representative (in terms of demographic factors such as race, color, national origin, handicapped condition, sex, and age) of population or community for which the materials are intended.

(3) *Function.* In reviewing materials, the Advisory Committee shall:

(i) Consider the educational and cultural backgrounds of individuals to whom the materials are addressed;

(ii) Consider the standards of the population or community to be served with respect to such materials;

(iii) Review the content of the material to assure that the information is factually correct;

(iv) Determine whether the material is suitable for the population or community to which it is to be made available; and

(v) Establish a written record of its determinations.

supervises the administration of any program receiving Federal financial assistance, or (3) person who receives, under any program receiving Federal assistance, compensation for services, who coerces or endeavors to coerce any person to undergo an abortion or sterilization procedure by threatening such person with the loss of, or disqualification for the receipt of, any benefit or service under a program receiving Federal financial assistance shall be fined not more than $1,000 or imprisoned for not more than one year, or both.

§ 59.7 What criteria will the Department of Health and Human Services use to decide which family planning services projects to fund and in what amount?

(a) Within the limits of funds available for these purposes, the Secretary may award grants for the establishment and operation of those projects which will in the Department's judgment best promote the purposes of section 1001 of the Act, taking into account:

(1) The number of patients and, in particular, the number of low-income patients to be served;

(2) The extent to which family planning services are needed locally;

(3) The relative need of the applicant;

(4) The capacity of the applicant to make rapid and effective use of the Federal assistance;

(5) The adequacy of the applicant's facilities and staff;

(6) The relative availability of non-Federal resources within the community to be served and the degree to which those resources are committed to the project; and

(7) The degree to which the project plan adequately provides for the requirements set forth in these regulations.

(b) The Secretary shall determine the amount of any award on the basis of his estimate of the sum necessary for the performance of the project. No grant may be made for less than 90 percent of the project's costs, as so estimated, unless the grant is to be made for a project which was supported, under section 1001, for less than 90 percent of its costs in fiscal year 1975. In that case, the grant shall not be for less than the percentage of costs covered by the grant in fiscal year 1975.

(c) No grant may be made for an amount equal to 100 percent of the project's estimated costs.

§ 59.8 How is a grant awarded?

(a) The notice of grant award specifies how long HHS intends to support the project without requiring the project to recompete for funds. This period, called the project period, will usually be for 3 to 5 years.

(b) Generally the grant will initially be for 1 year and subsequent continuation awards will also be for 1 year at a time. A grantee must submit a separate application to have the support continued for each subsequent year. Decisions regarding continuation awards and the funding level of such awards will be made after consideration of such factors as the grantee's progress and management practices, and the availability of funds. In all cases, continuation awards require a determination by HHS that continued funding is in the best interest of the Government.

(c) Neither the approval of any application nor the award of any grant commits or obligates the United States in any way to make any additional, supplemental, continuation, or other award with respect to any approved application or portion of an approved application.

§ 59.9 For what purpose may grant funds be used?

Any funds granted under this subpart shall be expended solely for the purpose for which the funds were granted in accordance with the approved application and budget, the regulations of this subpart, the terms and conditions of the award, and the applicable cost principles prescribed in subpart Q of 45 CFR part 74.

§ 59.10 What other HHS regulations apply to grants under this subpart?

Attention is drawn to the following HHS Department-wide regulations which apply to grants under this subpart. These include:

42 CFR Part 50, Subpart D—Public Health Service grant appeals procedure

42 CFR Part 122, Subpart E—Health Systems Agency review of certain proposed uses of Federal health funds

45 CFR Part 16—Procedures of the Departmental Grant Appeals Board

45 CFR Part 19—Limitations on payment or reimbursement for drugs

45 CFR Part 74—Administration of grants

45 CFR Part 80—Nondiscrimination under programs receiving Federal assistance through the Department of Health and Human Services effectuation of Title VI of the Civil Rights Act of 1964

45 CFR Part 81—Practice and procedure for hearings under Part 80 of this Title

45 CFR Part 84—Nondiscrimination on the basis of handicap in programs and activities receiving or benefiting from Federal financial assistance

45 CFR Part 91—Nondiscrimination on the basis of age in HHS programs or activities receiving Federal financial assistance

§ 59.11 Confidentiality.

All information as to personal facts and circumstances obtained by the project staff about individuals receiving services must be held confidential and must not be disclosed without the individual's consent, except as may be necessary to provide services to the patient or as required by law, with appropriate safeguards for confidentiality. Otherwise, information may be disclosed only in summary, statistical, or other form which does not identify particular individuals.

§ 59.12 Inventions or discoveries.

(a) A project grant award is subject to the regulations of HHS as set forth in 45 CFR parts 6 and 8, as amended. These regulations shall apply to any activity of the project for which grant funds are used, whether the activity is part of an approved project or is an unexpected byproduct of that project.

(b) The grantee and the Secretary shall take appropriate measures to assure that no contracts, assignments, or other arrangements inconsistent with the grant obligation are continued or entered into and that all personnel involved in the grant activity are aware of and comply with such obligations.

§ 59.13 Additional conditions.

The Secretary may, with respect to any grant, impose additional conditions prior to or at the time of any award, when in the Department's judgment these conditions are necessary to assure or protect advancement of the approved program, the interests of public health, or the proper use of grant funds.

[FR Doc. 93-2733 Filed 2-3-93; 1:18 pm]

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